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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|------------------------------|------------------|
| 09/980,614 | 04/17/2002 | Yi Li | 60020-5001-US | 8325 |
| 23973 7590 07/13/2007 DRINKER BIDDLE & REATH ATTN: INTELLECTUAL PROPERTY GROUP ONE LOGAN SQUARE 18TH AND CHERRY STREETS PHILADELPHIA, PA 19103-6996 | | | EXAMINER AZPURU, CARLOS A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
| | | | MAIL DATE | DELIVERY MODE |
| | | | 07/13/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|----------------------------------|--|
| Office Action Summary | Application No. 09/980,614 | Applicant(s) LI ET AL. | |
| | Examiner Carlos A. Azpuru | Art Unit 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment and terminal disclaimer filed
04/02/2007.

The rejections under the judicially created doctrine of obviousness-type double patenting are hereby withdrawn in view of the newly filed terminal disclaimer.

The following are new rejections of the claims:

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3, 15, and 16 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The newly amended claims 1-3 refer to "penumbral central nervous tissue" which has no support in the specification. Although it is understood that the word penumbral refers to outlying sections, the newly amended term appears to refer to a

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specific portion of the central nervous system which is not supported by the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5, 11- 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims refer to penumbral tissue which appears to refer to a specific tissue, however this term has no specific meaning. It is understood that applicant is referring to tissues adjacent to, or penumbral to the lesion, but there is no particular meaning attached to "penumbral tissue" Correction is requested.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Azizi et al.

Azizi et al disclose transplantation of human marrow stromal cells and astrocyte precursors (neurospheres) (see Abstract; page 3910, Results). The transplanted cells behaved like endogenous CNS stem cells (see Migration of Implanted Cells, page 3911). Finally, Azizi et al suggest the use of the transplant in the treatment of various disease. Azizi et al teaches the administration of the same cells, by the same route, to the same organ, and said cells migrate in the same way as claimed in the instant application. Azizi et al further provide the suggestion to use said implants in the treatment of various CNS diseases. While Azizi et al does indeed use a healthy brain, the mechanism of action of these migrated cells is an inherent property of these cells, not the condition of the brain. They would function in the same way regardless of the condition of the brain. Further, while applicant adds the term "penumbral", this term merely refers to adjacent portions of the CNS as disclosed by Azizi et al. There is no specific "penumbral tissue" of the brain which differentiates the instant claims from the generic disclosure of Azizi et al to transplant these cells into CNS tissue, and for the same therapeutic purpose. Azizi et al does indeed show, survival, engraftment, and migration of these stromal cells. While Azizi et al also deliver their cells to a healthy CNS, there is no showing that delivery to damaged or diseased tissue would function any differently. Further, there is a clear suggestion to treat CNS diseases by Azizi et al. It is agreed that Azizi et al do not teach that the transplanted cells would differentiate

into parenchymal cells in the brain. However, the evidence presented by the Azizi et al paper indicates that these transplanted cells do indeed become differentiated once they are transplanted given that they are said to behave like endogenous CNS cells. The process of differentiation of these cells is therefore expected once the cells are isolated, transplanted and migration takes place. Indeed, this migration appears to be evidence of differentiation. Therefore, barring a showing that tis transplantation would behave differently in healthy vs damaged central nervous tissue, those of ordinary skill would have expected similar therapeutic results from the transplantation of cells as disclosed by Azizi et al. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of Azizi et al.

Response to Arguments

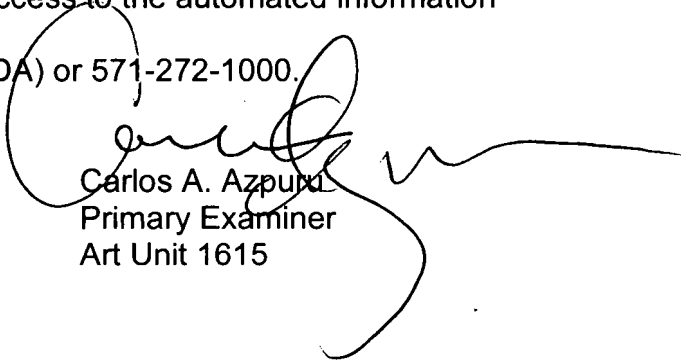
Applicant's arguments filed 04/02/2007 have been fully considered but they are not persuasive.

While applicant argues that Azizi et al does not support transplantation penumbral (adjacent to a lesion, the reference does indeed disclose transplantation and then migration of the cells in question in order to treat CNS disease). Therefore, the use of the term "penumbral" does not differentiate from the disclosure of Azizi et al to place these cells in central nervous tissue. While the reference may not anticipate the instant method, it certainly suggests it to those of ordinary skill and the rejection has been rewritten to reflect this.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz